

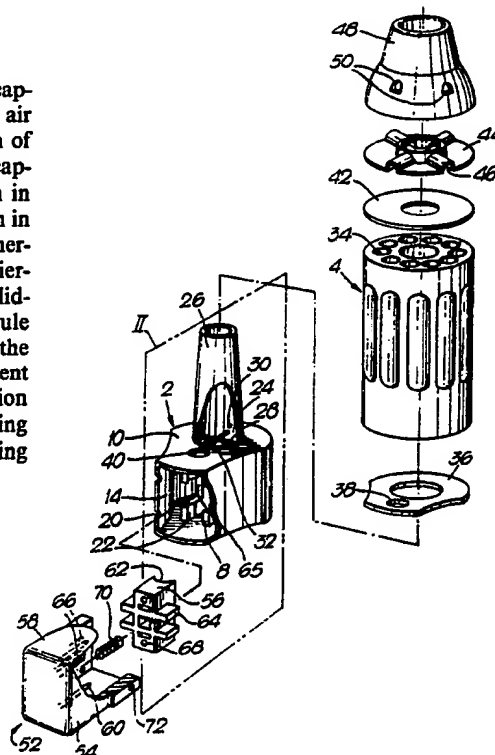


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB91/01357 (22) International Filing Date: 9 August 1991 (09.08.91) (30) Priority data: 9017654.6 11 August 1990 (11.08.90) GB 9024149.8 7 November 1990 (07.11.90) GB (71) Applicant (for all designated States except US): FISONS PLC [GB/GB]; Fison House, Princes Street, Ipswich, Suffolk IP1 1QH (GB). (72) Inventors; and (75) Inventors/Applicants (for US only) : MINSHULL, Stephen, John [GB/GB]; 11 Rhodes Close, Haslington, Nr. Crewe, Cheshire CW1 1ZF (GB). HART, John, Leck [GB/GB]; 74 Cow Lane, Bramcote, Nottinghamshire NG9 3BB (GB). KENT, Steven [GB/GB]; 13 Ashburn Grove, Heaton Norris, Stockport, Cheshire SK4 2PT (GB). SHEPHERD, Michael, Trevor [GB/GB]; 14 Dingle Lane, Sandbach, Nr. Crewe CW11 0ES (GB).		(74) Agent: WRIGHT, Robert, Gordon, McRae; Fisons plc, 12 Derby Road, Loughborough, Leicestershire LE11 0BB (GB). (81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report.</i>

(54) Title: INHALATION DEVICE**(57) Abstract**

A medicament inhalation device for use with medicament capsules comprises a capsule emptying chamber (12) provided with an air inlet (18) and an air outlet (24), and a drawer (52) for introduction of capsules (C) to the chamber, the drawer (52) being provided with capsule piercing means (60) and moveable between a loading position in which a capsule (C) may be placed therein and an inhalation position in which the capsule (C) is delivered to the emptying chamber (12), wherein the drawer (52) comprises a body portion (54) upon which the piercing means (60) are mounted, and a pushing portion (56) which is slidably mounted on the body portion and which bears against the capsule (C) during movement of the drawer (52) from the loading position to the inhalation position, the arrangement being such that relative movement of the body portion (54) and the pushing portion (56) in the inhalation position of the drawer results in the drawer (52) adopting a piercing configuration in which the capsule (C) is pierced by the capsule piercing means (60).



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INHALATION DEVICE

This invention relates to an improved medicament inhalation device, more particularly to such a device for use with
5 medicament capsules.

European Patent Application No 406893 (to Somova SpA, published after the priority date of the present invention) discloses a medicament inhalation device for use with
10 medicament capsules, comprising a capsule emptying chamber provided with an air inlet and an air outlet, and a drawer for introduction of capsules to the chamber, the drawer being provided with capsule piercing means and moveable between a loading position in which a capsule may be placed
15 therein and an inhalation position in which the capsule is delivered to the emptying chamber. In one embodiment of the device, the piercing means are slidably mounted on the drawer, and must be actuated in an additional action following introduction of a capsule to the emptying
20 chamber. This may be difficult for those with impaired hand movement, for example the elderly.

In the device mentioned above, capsules are dispensed into the drawer from a capsule magazine with their longitudinal
25 axis in an upright position. It has been found that more than one capsule may be dispensed into the drawer at a time, creating the risk of overdosing if both capsules are pierced, or jamming of the drawer. A further disadvantage of this device is a tendency for capsules dispensed into
30 the drawer to fall into the emptying chamber horizontally, which also results in jamming of the drawer. In addition, capsules sometimes move vertically once in the chamber, leading to ineffective piercing by the piercing means.

35 We have now devised an improved mechanism for the transport and piercing of medicament capsules in a medicament inhalation device which is especially useful in inhalation

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devices of the type disclosed in European Patent Application No 406893.

According to the present invention, there is provided a medicament inhalation device for use with medicament capsules, comprising a capsule emptying chamber provided with an air inlet and an air outlet, and a drawer for introduction of capsules to the chamber, the drawer being provided with capsule piercing means and moveable between a loading position in which a capsule may be placed therein and an inhalation position in which the capsule is delivered to the emptying chamber, characterized in that the drawer comprises a body portion upon which the piercing means are mounted, and a pushing portion which is slidably mounted on the body portion and which bears against the capsule during movement of the drawer from the loading position to the inhalation position, the arrangement being such that relative movement of the body portion and the pushing portion in the inhalation position of the drawer results in the drawer adopting a piercing configuration in which the capsule is pierced by the capsule piercing means.

The device of the invention has the advantage that transport and piercing of a capsule may be achieved in one action which firstly moves the drawer from the loading position to the inhalation position and then causes adoption of the piercing configuration by relative movement of the body portion and the pushing portion. The device will be more readily operated by those with impaired hand movement, and will be more convenient for others, than prior art devices which require more than one action to achieve transport and piercing of a capsule.

We prefer the pushing portion to be biased away from the body portion of the drawer by biasing means, for example a compression spring. The biasing means may act to automatically reverse the relative movement of the body

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portion and the pushing portion which results in adoption of the piercing configuration, so that inhalation may take place through the device.

- 5 Desirably, the pushing portion is restrained by a stop when the drawer is in the inhalation position. The stop (or stops) may be provided adjacent to the emptying chamber. In this case, appropriate movement of the body portion of the drawer results in adoption of the piercing
10 configuration of the drawer.

Preferably, the piercing means are covered by the pushing portion except when the drawer is in (or approaching) the piercing configuration. This may be achieved by providing
15 through-going apertures or channels in the pushing portion which receive the piercing means when the drawer is not in the piercing position, and which allow the piercing means to pass through during relative movement of the body portion and the pushing portion.

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We prefer the piercing means to comprise two rods each having a sharpened end. The ends of the rods may be sharpened to a point or a blade. The rods may be formed in one piece, for example they may be parts of a U-shaped
25 double ended pin.

Advantageously, the capsule emptying chamber has a capsule entrance whose width is less than the diameter of the capsule. This restricts the movement of a capsule between
30 arrival in the drawer and introduction to the chamber. For example, such a feature may prevent capsules falling into a horizontal position when they are intended to be transported and pierced in a vertical position. Where biasing means are also provided, their stiffness is
35 preferably sufficiently great that the resistance offered by a capsule as it is urged through the capsule entrance by the pushing portion does not result in a substantial

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- perturbation of the biasing means: for example where the biasing means is a compression spring, the spring is not substantially compressed.
- 5 Preferably, devices of the invention comprise a capsule magazine from which capsules are dispensed into the body portion of the drawer, for example by falling under gravity.
- 10 Controlled, individual dispensing of capsules is facilitated by provision of a shutter member on the body portion of the drawer, which closes off the drawer from the magazine when the drawer is not in the loading position. This prevents further capsules entering the drawer, which
- 15 could result in jamming of the drawer or an overdose being administered to a patient. Furthermore, where the device comprises a capsule magazine, the shutter member prevents ingress of moisture to the capsules remaining in the magazine. The shutter member is preferably arranged so
- 20 that it may further act to restrain movement of the capsule in the emptying chamber during piercing of the capsule.

Conventional means for dispersing powder in an entrained airstream may be provided in the air outlet, for example

25 grids through which the airstream passes.

According to a second aspect of the invention, there is provided a medicament inhalation device for use with medicament capsules, comprising a capsule emptying chamber

30 provided with an air inlet and an air outlet, and a drawer for introduction of capsules to the chamber, the drawer being provided with capsule piercing means and moveable between a loading position in which a capsule may be placed therein and an inhalation position in which the capsule is

35 delivered to the emptying chamber, characterized in that the air outlet is provided with one or more air inlets.

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We prefer the air outlet to be provided with a pair of diametrically opposed air inlets adjacent to the capsule emptying chamber, and two pairs of diametrically opposed air inlets at the end of the air outlet remote from the capsule emptying chamber.

It has been found that devices according to this aspect of the invention are able to deliver medicament to a patient with a much greater proportion of the particles having a size in the respirable range. By "respirable range" we mean sizes sufficiently small to penetrate deep into the lungs during inhalation, ie those having a mass median diameter in the range 1-10 μ m. In addition, it has been found that such devices require less inhalatory effort by a patient to inhale through them.

We especially prefer devices which incorporate both aspects of the invention.

A preferred embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is an exploded perspective view, partly cut away, of a medicament inhalation device according to the invention which comprises a base portion and a capsule magazine;

Figure 2 is a cross sectional view in the plane II-II-II of Figure 1 of the base portion of the device with a drawer in a loading position;

Figure 3 is a cross sectional view along the line III-III of Figure 2;

Figure 4 is a view similar to that of Figure 2, but with the drawer in an inhalation position;

Figure 5 is a cross sectional view along the line V-V of Figure 4;

Figure 6 is a view similar to that of Figure 2, but with the drawer in a capsule piercing configuration; and

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Figure 7 is a cross sectional view along the line VII-VII of Figure 6.

Referring first to Figure 1, a medicament inhalation device comprises a generally cylindrical base portion 2, upon which is coaxially and rotatably mounted a cylindrical capsule magazine 4.

Base portion 2 defines an inner space 6 which is more readily seen in Figures 2-7. A cuboid member 8 depends from the upper wall 10 of base portion 2 into space 6. Member 8 defines an upright cylindrical capsule emptying chamber 12 towards its rear end which communicates with an opening 14 in the front of base portion 2 via an upright rectangular passageway 16 whose width is slightly less than the diameter of a capsule C. Two tangential air inlets 18 are provided at the base of chamber 12 which communicate with space 6. Space 6 in turn communicates with the atmosphere via air inlets 20 which take the form of niches in the side wall of opening 14. Passageway 16 is also provided with an upright cylindrical capsule receiving chamber 22 towards its front end.

Capsule emptying chamber 12 is provided with an air outlet 24 which extends into a cylindrical shaft 26 which projects vertically from upper wall 10 of base portion 2. A cross piece 28 delimits chamber 12 from air outlet 24, and serves to prevent capsule C escaping from chamber 12 through air outlet 24, as well as producing air turbulence which disperses entrained medicament, during inhalation. Two diametrically opposed air inlets 30 empty into air outlet 24 just above cross piece 28. Air inlets 30 communicate with space 6 via passageways 32 which commence as vertical channels on the rear surface of member 8 and run through wall 10 and the wall of shaft 26. The air admitted by air inlets 30 serves to disperse entrained medicament during inhalation, and also to reduce the inhalatory effort

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required to inhale through the device. A grid (not shown) is provided across air outlet 24 towards the top of shaft 26, which also serves to disperse entrained medicament during inhalation.

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Magazine 4 is mounted on shaft 26, and is provided with ten circumferentially arranged vertical bores 34 which are each adapted to receive three medicament capsules. Magazine 4 abuts a gasket 42 attached to wall 10 so as to make an air
10 tight seal. The bottom opening of each bore 34 may be brought into communication successively with aligned openings 38 and 40 in gasket 36 and wall 10 respectively by rotation about shaft 26. An annular gasket 42 seals the upper ends of bores 34, and an annular plate 44 provided
15 with four downwardly facing channels 46 is retained on gasket 36 by mouthpiece 48 which makes a snap fitting connection with magazine 4. Channels 46 define two pairs of diametrically opposed air inlets which empty into the upper portion of air outlet 24 and communicate with the
20 atmosphere via openings 50 in the mouthpiece. The air admitted by channels 46 acts similarly to that admitted by air inlets 30 mentioned above.

A drawer 52 is slidably mounted on member 8 and comprises a
25 body portion 54 and a pushing portion 56 which is slidably mounted on body portion 54. A horizontally disposed compression spring 70 connects body portion 54 to pushing portion 56.

30 Body portion 54 has a generally U-shaped cross section, with a shutter 58 extending horizontally from the top of its front end, and a U-shaped double ended pin 60 mounted therein. Shutter 58 is received by a space between the front portion of member 8 and wall 10, and the base of body
35 portion 54 is received by a space between member 8 and the base of base portion 2.

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Pushing portion 56 is generally cuboid, with a concave back surface 62, and a pair of lateral wings 64 on each side surface which are received by channels 66 on the inner surface of the side walls of body portion 54. Lateral wings 64 pass through lateral slots 65 formed in the side walls of member 8 when drawer 52 is in the inhalation position. The two ends of pin 60 are slidably received by two bores 68 which run through pushing portion 56. Each side wall of body portion 54 has a through going bore 72 through which space 6 communicates with air inlets 18 when the drawer is in the inhalation position.

The device is operated as follows. With drawer 52 in the loading position shown in Figures 2 and 3, capsule C may fall under gravity from its bore 34 in magazine 4 into capsule receiving chamber 22 through opening 38 in gasket 36 and opening 40 in wall 10. Drawer 52 is then pushed radially inward by applying pressure to the front end of body portion 54. As this movement takes place, shutter 58 passes under opening 40 and prevents a second capsule from entering drawer 52. Also, force is transmitted via spring 70 to pushing portion 56 which bears against capsule C with its concave rear surface 62. Capsule C is consequently urged through passageway 16, and because the width of the passageway is less than the diameter of capsule C, the capsule remains in an upright position which is desirable for optimum piercing and avoidance of jamming of the drawer. The stiffness of spring 70 is such that the force necessary to urge capsule C through passageway 16 does not compress it substantially.

In the inhalation position of the drawer shown in Figures 4 and 5, capsule C is delivered to capsule emptying chamber 12, and surface 62 of pushing portion 56 makes up part of the vertical wall of chamber 12. Also, lateral wings 64 of pushing portion 56 abut the end of slots 65 in member 8.

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Further inward movement of body portion 54 results in relative movement of body portion 54 and pushing portion 56 since pushing portion 56 is unable to move further inward because of its abutment with the end of slot 65. Compression of spring 70 accompanies this relative movement. The two ends of pin 60 move through bores 68 and penetrate into capsule emptying chamber 12, and shutter 58 passes over the top of chamber 12 which restricts the vertical movement of capsule C. Pin 60 first moves capsule C into a vertical position and then penetrates the capsule in the piercing configuration of the drawer which is shown in Figures 6 and 7, producing two openings. The pressure on body portion 54 is then released and spring 70 urges body portion 54 radially outward so that the device attains once again the inhalation position shown in Figures 4 and 5.

A patient then places his lips over mouthpiece 48 and inhales. Air is drawn through air inlets 20 into space 6 and from there into capsule emptying chamber 12 through bores 72 and air inlets 18. This movement of air causes the capsule to rotate about its longitudinal axis and undergo reciprocating movement along that axis, causing the powdered medicament to empty into chamber 12 through the openings made by the two ends of pin 60. The medicament is then entrained by the airstream and passes through air outlet 24 and into the patient. During inhalation, air is also drawn from space 6 into passageways 32 and through openings 50 to channels 46, from where it passes into air outlet 24 as described above.

To administer the contents of a subsequent capsule, body portion 54 is drawn radially outward to the loading position shown in Figures 2 and 3. During this movement, the emptied capsule leaves the device by falling through opening 74 in base portion 2, which is coaxial with capsule emptying chamber 12. On reaching the loading position, the

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next capsule falls into capsule receiving chamber 22, and the operation described above is repeated.

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CLAIMS:

1. A medicament inhalation device for use with medicament capsules, comprising a capsule emptying chamber provided with an air inlet and an air outlet, and a drawer for introduction of capsules to the chamber, the drawer being provided with capsule piercing means and moveable between a loading position in which a capsule may be placed therein and an inhalation position in which the capsule is delivered to the emptying chamber,
characterized in that the drawer comprises a body portion upon which the piercing means are mounted, and a pushing portion which is slidably mounted on the body portion and which bears against the capsule during movement of the drawer from the loading position to the inhalation position, the arrangement being such that relative movement of the body portion and the pushing portion in the inhalation position of the drawer results in the drawer adopting a piercing configuration in which the capsule is pierced by the capsule piercing means.
2. A device according to claim 1, wherein the pushing portion is biased away from the body portion of the drawer by biasing means.
3. A device according to claim 1 or claim 2, wherein the pushing portion is restrained by a stop when the drawer is in the inhalation position.
4. A device according to any one of the preceding claims, wherein the piercing means are covered by the pushing portion when the drawer is not in the piercing configuration.
5. A device according to any one of the preceding claims, wherein the piercing means comprise two rods each having a sharpened end.
6. A device according to any one of the preceding claims, wherein the chamber has a capsule entrance whose width is less than the diameter of the capsule.
7. A device according to any one of the preceding claims,

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which further comprises a capsule magazine from which capsules are dispensed into the body portion of the drawer.

8. A device according to claim 7, wherein the body portion of the drawer is provided with a shutter member which closes off the drawer from the magazine when the drawer is not in the loading position.

9. A device according to any one of the preceding claims, wherein the air outlet is provided with one or more air inlets.

10. A medicament inhalation device for use with medicament capsules, comprising a capsule emptying chamber provided with an air inlet and an air outlet, and a drawer for introduction of capsules to the chamber, the drawer being provided with capsule piercing means and moveable between a loading position in which a capsule may be placed therein and an inhalation position in which the capsule is delivered to the emptying chamber,

characterized in that the air outlet is provided with one or more air inlets.

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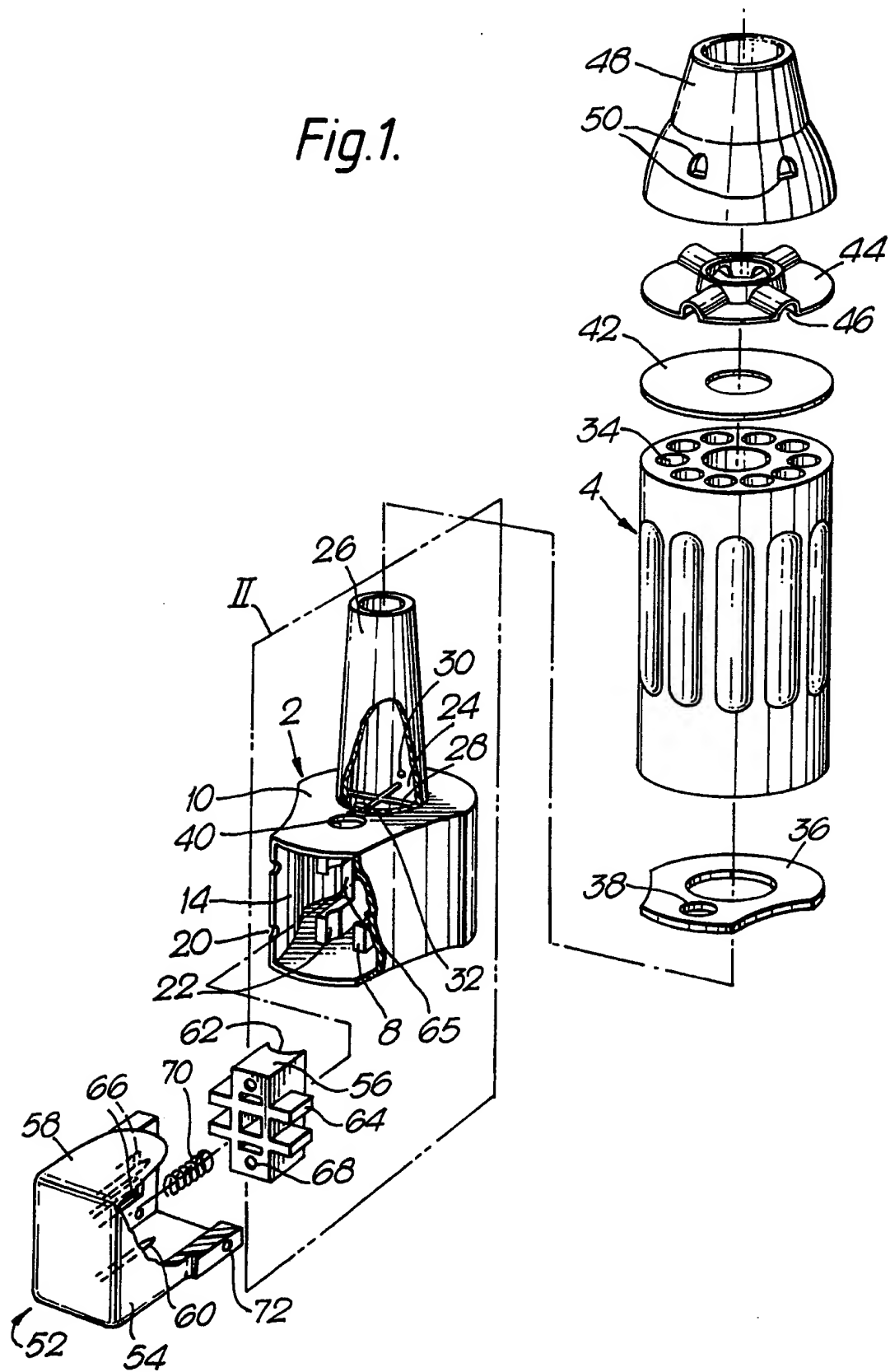
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Fig.1.



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Fig. 2.

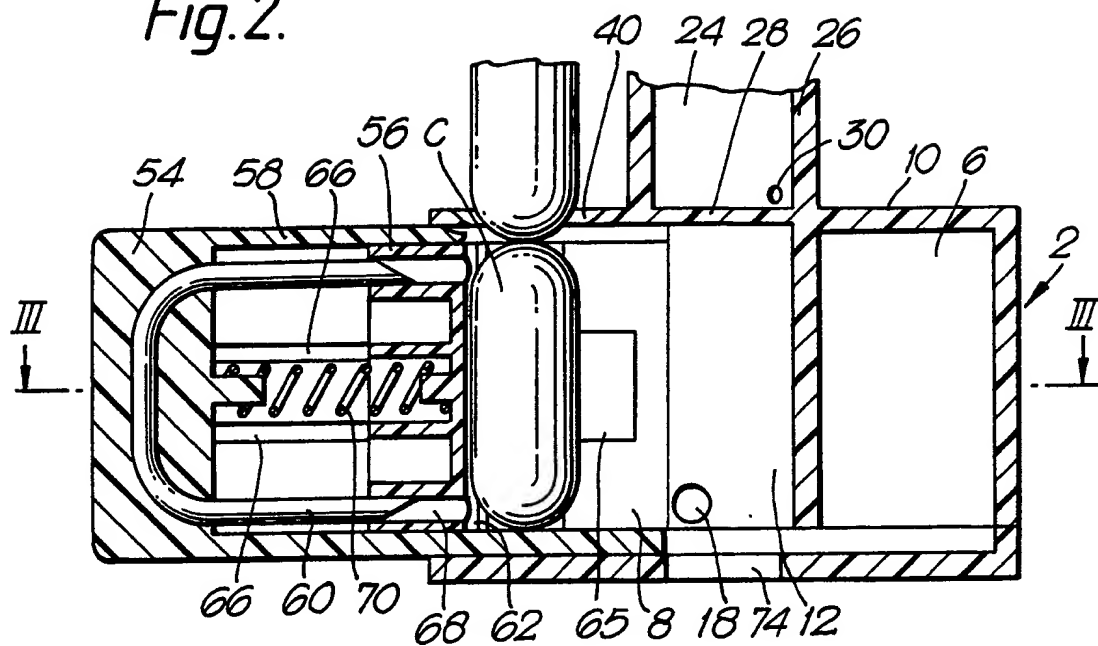
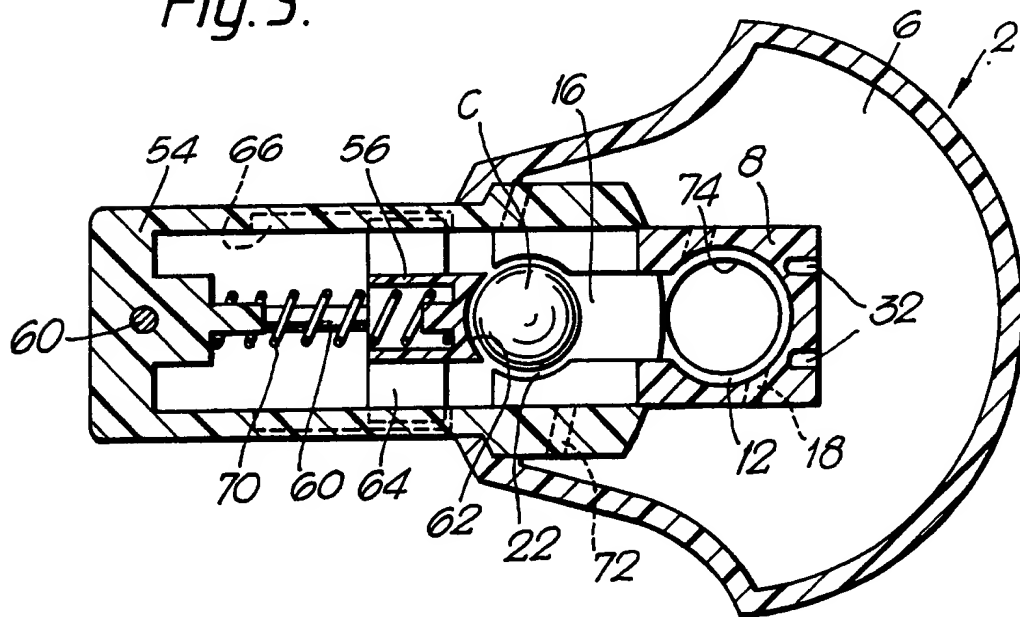
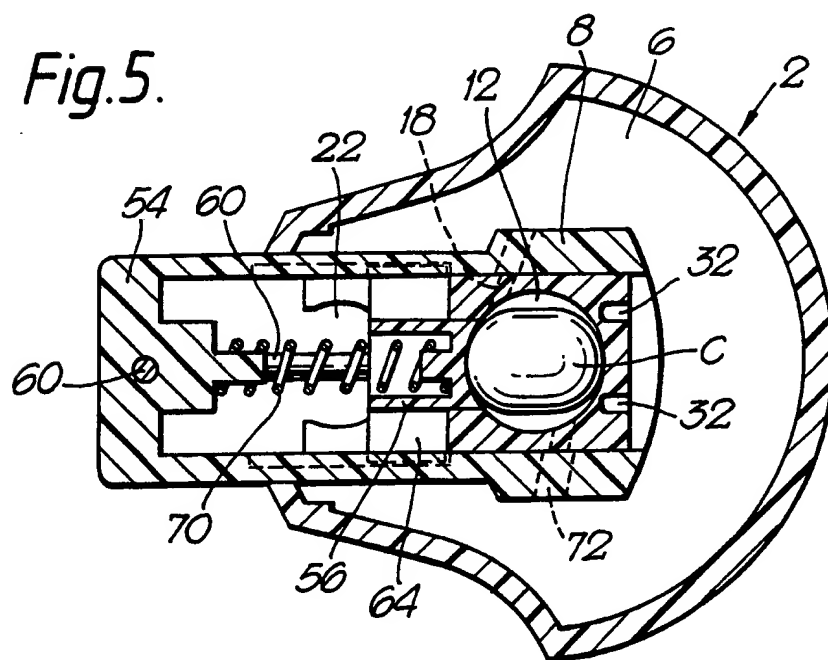
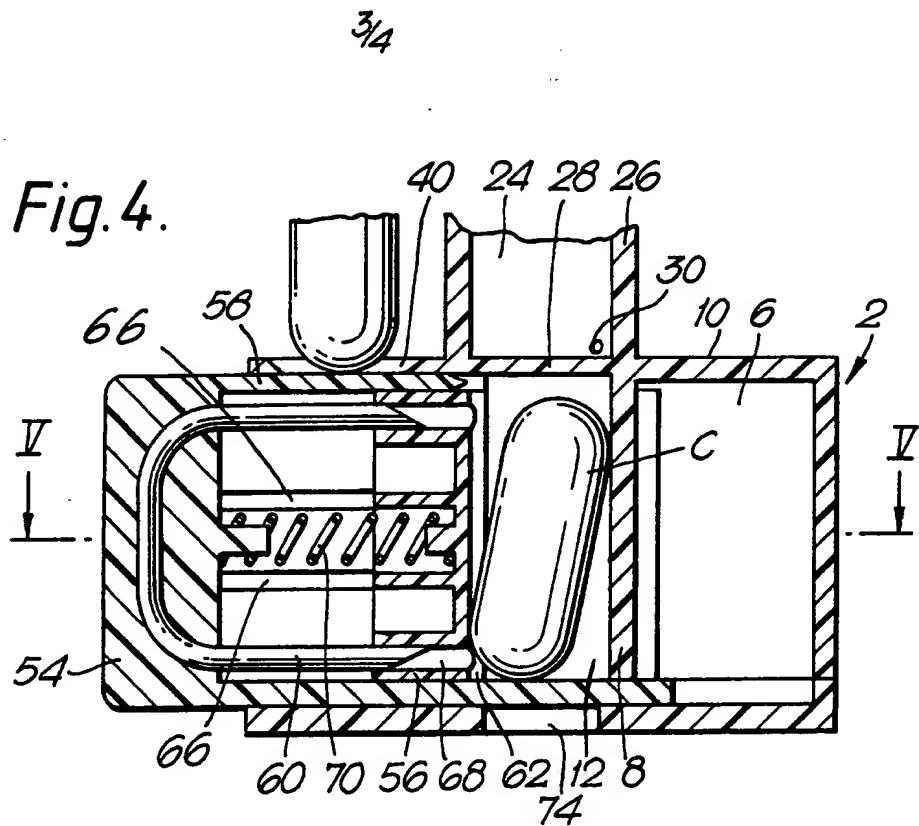


Fig. 3.

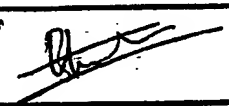




INTERNATIONAL SEARCH REPORT

PCT/GB 91/01357

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M15/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
P,Y	EP,A,406 893 (SOMOVA SPA) January 9, 1991 cited in the application	10
A	see abstract; figures 20-24 see column 7, line 8 - line 49	1
Y	FR,A,1 551 053 (FISONS PHARMACEUTICALS LIMITED) December 27, 1968 see page 3, left column, line 9 - line 21 see page 3, right column, line 19 - line 28; figure 1	10
A	DE,A,2 704 574 (ALLEN & HANBURY LTD) August 11, 1977 see claim 1; figures	1,10
A	EP,A,147 755 (BOEHRINGER INGELHEIM KG) July 10, 1985 see page 6, line 1 - line 18; figure 1	1,10
<p>⁹ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
21 OCTOBER 1991	29 OCT 1991	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	ZEINSTRÄ H. 	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9101357
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